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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,232

06/30/2006

Stephen D. Goble

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210 7590 12/30/2009
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EXAMINER

CHANDRAKUMAR, NIZAL S

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

12/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,232	Applicant(s) GOBLE ET AL.	
	Examiner NIZAL S. CHANDRAKUMAR	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,5,7,13-16,19,20,24,25 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 6, 8-12, 17, 18, 21-23, 26-28, 34, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/18/2008, 06/30/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/US04/43777 12/29/2004 which claims benefit of 60/533,892 01/02/2004.

Election/Restrictions

Applicant's election with traverse of

Group 4, claim(s) 1-38 in part, drawn to compounds of formula Ib or Ic wherein Z is C, in the reply filed on 10/02/2009 is acknowledged. The traversal is on the ground(s) that the structural moieties in the compounds of the reference cited by the examiner are different from the instantly claimed compounds. The invariant structural unit common to all the group is N-aminoalkyl or N-aminoacyl benzamides/benzylamides/phenylureas well known in the chemical art; thus they are not contribution over the prior art. As such applicant arguments is not found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

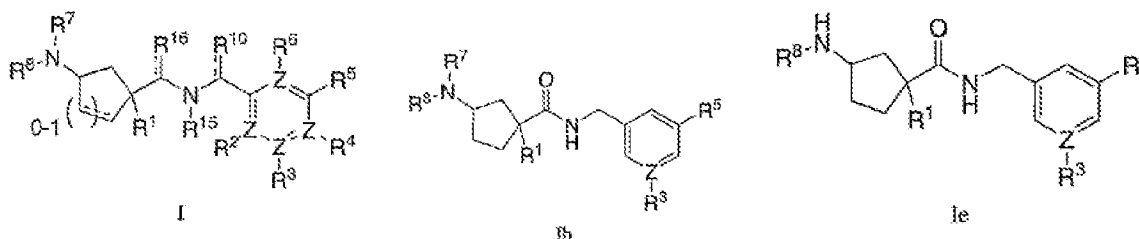
Applicant identifies claims 1, 3, 6, 8-28 and 31-38, as containing elected subject matter. However, claims 3, 6, 8-12, 17, 18, 21-23, 26-28, 34, 35 read on the elected group 4. Claims 36-38 replaced with new claim 39 (see below). Claim 2, 4, 5, 7, 13-16, 19, 20, 24, 25, 29-32, 39 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/02/2009.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Objection

Formula I of claim 1 and the elected formulae Ib and Ic are shown below for comparison.



Applicant is requested to correct the claim dependency in view of the elected group of formulae.

There are five R groups R1, R3, R5, R7, and R8 in the elected group formulae. In the elected group claims relating to these variables are: 1, 3, 6, 8-12, 17, 18, 21-23, 26-28 and 34, 35.

Elected Group of formulae do not contain, for example, R2, R4, R6 variables.

Appropriate correction of claims (or deletion of claims) is required. It is suggested that in formulae Ib and Ic Z is replaced with C or the structure redrawn as per the elected group 4.

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Claims 3, 6, 8-12, 17, 18, 21-23, 26-28 and 34, 35-38 are Examined to the extent that they read on the elected group, that is formula Ib and Ic and methods relating to the compounds of these formulae. Deleting non-elected subject matter is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6, 8-12, 17, 18, 21-23, 26-28, 34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language 'pharmaceutically acceptable salts thereof and individual diastereomer thereof' is unclear. It is suggested that the term

"and" in this phrase is replaced with --or--

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

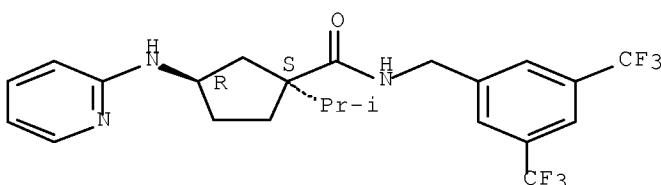
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1, 3, 6, 8-12, 17, 18, 21-23, 26-28, 34, 35 and (new claim 39 *vide supra*) rejected under 35 U.S.C. 102(e) as being anticipated by Abbadie et al WO 2004110376 (applicant provided; US priority date 06/06/2003, 12/22/2003).

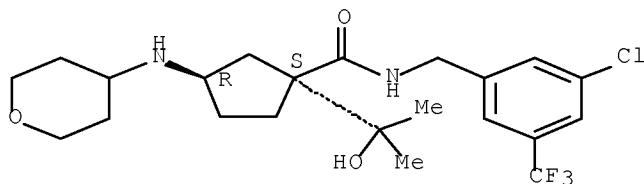
The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

R3= R5 = CF₃; R1 C3=alkyl, R7=H, R8= pyridyl



Corresponds to compound of claims 3, 6, 8, 9, 10, 21-23 (R5=CF₃), 26, 27 (R7 = H), 28

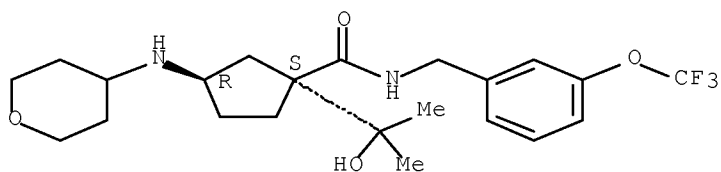
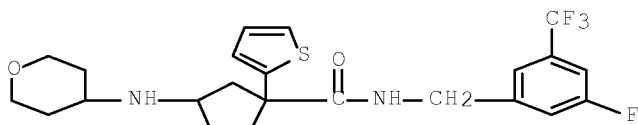
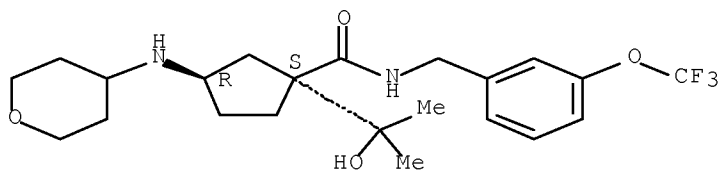
R8 is pyridyl



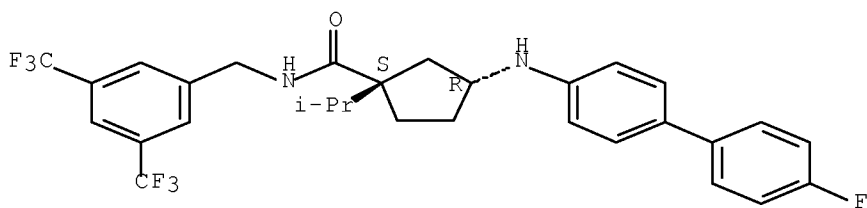
Likewise

Corresponds to compound of Claim 11

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Corresponds to compound of Claim 18 wherein R3 is H



Corresponds to compound of claim 34 row 4, first compound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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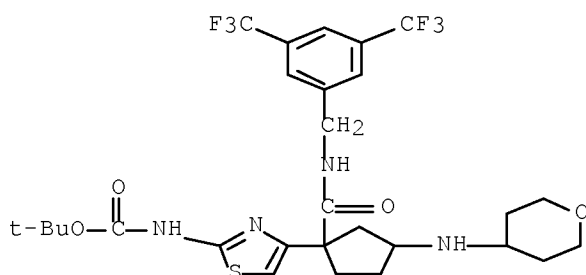
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 12 is rejected under 35 U.S.C. 102(a) as being anticipated by Butora et al.

US7390803.

Butora et al. teach



Corresponding to the compound of

claim 12, wherein R1 is substituted thiazolyl, R5=R3=CF3, R7 = H, R8 = heterocycle.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 6, 8-12, 17, 18, 21-23, 26-28, 34, 35 and (new claim 39 *vide infra*) rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 7390803, and US 7557124. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant claims and the claims of the issued patents are drawn to the compounds of similar structure; further the instant method of use claims are also same in the instant case and in the issued patent.

Regarding instant claims 36, 37, 38:

See Interview Summary filed 11/09/2009: In a telephone conversation on 11/06/2009, Attorney of record James L. McGinnis, agreed for the cancellation of instant claims 36-38 and addition of the new claim 39:

~~A method of treating an inflammatory or immunoregulatory disorder or disease comprising the administration of a therapeutically effective amount of the compound of claim 1 to a patient in need of treatment wherein said disorder or disease is rheumatoid arthritis.~~

As such, claims 36, 37 and 38 are indicated as cancelled in lieu of claim 39 and shown as rejected in view of the double patenting rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nizal S Chandrakumar/

Examiner, Art Unit 1625